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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,646	03/23/2001	Scott H. Jaeger	11506/3	4634

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EXAMINER	
KOPPIKAR, VIVEK D	
ART UNIT	**PAPER NUMBER**
3626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/815,646	JAEGER ET AL.	
	Examiner	Art Unit	
	Vivek D. Koppikar	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 1-9 and 16-18 have been examined in this application. This is a Final Office Action in response to the "Amendment" and "Remarks" filed on September 1, 2006.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (5828776).

(A) As per claim 1, Lee et al. closes a method for determining an overall level of confidence for a medical conclusion (i.e. normal or abnormal object) comprising the steps of:

a. determining at least one medical element from a set of medical data (i.e. object of medical image), wherein each element is associated with an impact parameter (i.e., set of measurements whose values determine the characteristic such as density or texture of an object) for the medical clinical conclusion. Lee et al., col. 17, lines 17-19, col. 18, lines 39-53.

b. for each medical element, generating a confidence parameter as a function of the medical clinical conclusion. Lee et al., col. 5, lines 35-45.

As per the step for determining an overall level of confidence parameter as a function of each of the confidence parameters and the associated impact values. It is unclear if Lee discloses this step. However, Lee teaches on col. 19, lines 5-8 and on col. 20, lines 23-36 that confidence values can be combined and that an overall rating of a slide can be done by combing classification data and confidence factors. It would have been obvious to one having ordinary skill in the art at the time of the invention to include an over rating or overall level of confidence parameter with the motivation of providing an evaluation of the specimen as a whole. Lee, col. 19, lines 47-48.

(B) As per claim 7, Lee et al. discloses a system for determining an overall level of confidence for a medical conclusion (i.e.) comprising a processor adapted to :

a. determining at least one medical element from a set of medical data (i.e. object of medical image), wherein each element is associated with an impact parameter (i.e., set of measurements whose values determine the characteristic such as density or texture of an object) for the medical clinical conclusion (i.e. a conclusion if an object is normal or abnormal). Lee et al., col. 4, lines 47-48, col. 17, lines 17-19, col. 18, lines 39-53.

b. for each medical element, generating a confidence parameter as a function of the medical clinical conclusion. Lee et al., col. 5, lines 5-45.

As per the determination of an overall level of confidence parameter as a function of each of the confidence parameters and the associated impact values. It is unclear if Lee discloses this limitation. However, Lee teaches on col. 19, lines 5-8 and on col. 20, lines 23-36 that confidence values can be combined and that an overall rating of a slide

can be done by combing classification data and confidence factors. It would have been obvious to one having ordinary skill in the art at the time of the invention to include an over rating or overall level of confidence parameter with the motivation of providing an evaluation of the specimen as a whole. Lee, col. 19, lines 47-48.

(C) As per claim 3, Lee et al. discloses the confidence value as a function of a features measurement values on col. 18, lines 54-65.

(D) As per claim 4, Lee et al. teaches the fuzzy theory and membership function on col. 21, lines 54-57, col. 22, lines 9-10.

(E) As per claims 5, 6. Lee et al. discloses a linear combination function(s) defining confidence parameter as independent variable on col. 32, lines 13-32.

4. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of US Patent Number 6,267,722 to Anderson.

(F) As per claims 17, Lee in view of Anderson teach a system for determining an overall level of confidence for a medical clinical conclusion comprising:

a processor (Lee: Col. 4, Ln. 23-27);

a medical element database storing medical element data (Lee: Figure 5—Item 5100);

Lee does not teach the following features which are taught by Anderson:

a medical rules knowledge database storing medical rules correlating at least one medical element to the medical clinical conclusion (Anderson: Col. 14, Ln. 20-41); and

a membership confidence generator calculating the overall level of confidence that the medical element correlates to the medical clinical conclusion (Anderson: Col. 14, Ln. 20-41).

At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the features of Lee with these aforementioned features from Anderson with the motivation of having a means of comparing the test results to the test results which are derived from using other methods, as recited in Anderson (Col. 14, Ln. 36-41).

(G) As per claim 18, in the combined teachings of Lee in view of Anderson there is a criterion impact database storing a criterion impact factor quantifying the important of the medical element to the medical clinical conclusion (Col. 14, Ln. 20-41) and the membership confidence generator calculates the overall level of confidence as a function of the criterion impact factor, medical element and medical clinical conclusion (Col. 14, Ln. 20-41). The motivation for making this modification to the teachings of Lee is the same as set forth above in the rejection of claim 17.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. as applied to claim 1 above, and further in view of Friedman (6055494).

(A) As per claim 2, Lee et al fails to expressly recite the phrase parsing. This, however, is well known as evidenced by Friedman. See Friedman, the abstract, Fig. 1, col. 2, line 60 to col. 3, line 21. It would have been obvious to one having ordinary skill in the art to include phrase parsing into Lee et al with the motivation of expanding the applicability of the system to include processing/classifying of natural language medical data. Friedman, col. 1, lines 20-25.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 8, 9, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication 2003/0105731 to LaPointe.

(A) As per claim 8, Lapointe et al. discloses a method for determining an overall level of confidence for a medical conclusion (i.e. risk of preterm delivery) comprising the steps of:

a. storing a plurality of possible clinical conclusion (i.e. risk of preterm delivery), Lapointe, page 23, paragraph 0416, Figs 12,13, outputs A, B, Fig. 14, outputs C, D.

b. storing a plurality of medical essential elements (i.e. clinical data, patient's variables, patient history information). Lapointe et al., page 8, paragraph 0097, page 21, paragraphs 0034-0360.

c. for each clinical conclusion, storing a plurality of membership function(s) associating an essential element with a clinical conclusion. Lapointe et al., page 7, paragraph 0079, page 8, paragraph 0097.

d. storing impact parameter(s) associating a weight of an element toward the output/clinical conclusion. Lapointe et al., page 1, paragraph 0008, page 10, paragraphs 0110, 0112, 0116.

e. determining at least one relevant medical essential element. Lapointe et al., page 4, paragraph 0027.

f. generating an overall confidence parameter for the medical clinical conclusion as a function of the at least one relevant medical essential element, the associated membership function and the impact parameter. Lapointe et al Fig 11A, page 19, paragraphs 0311-0313 wherein the medical conclusion(s) in this clinical application are. a low, high or moderate risk of preterm delivery within a time frame, and the calculated risk value for associated interpretations (i.e. low, high or moderate) representing the confidence parameter of the conclusion(s).

(B) As per claim 9, Lapointe et al. discloses a method for determining an overall level of confidence for a medical conclusion (i.e.. a low, high or moderate risk of preterm delivery within a time frame) comprising the steps of:

a. storing at least one membership function relating a medical element(s) (i.e. clinical data, patient's variables, patient history information) with a membership confidence value (i.e. in a binary form or quantitative/continuous values) for a clinical conclusion. Lapointe et al., page 7, paragraph 0079, page 8, paragraph 0097.

b. storing a criterion impact parameter representing an important of an medical element with respect to the clinical conclusion (i.e. a low, high or moderate risk of preterm delivery within a time frame) for each membership function. Lapointe et al. page

10, paragraphs 0110, 0113.

c. determining an overall confidence value (i.e., calculated risk values and its interpretations such as low, high or moderate) for a clinical conclusions (i.e.. a low, high or moderate risk of preterm delivery within a time frame) as a function of at least one membership function and at least one criterion impact parameter. Lapointe et al., Fig. 11A, page 19, paragraphs 0311-0313.

(C) As per claim 16, Lapointe et al. discloses a method for determining an overall level of confidence for a conclusion (i.e.. a low, high or moderate risk of preterm delivery within a time frame) comprising the steps of:

a. determining at least one element from a set of data (i.e. clinical data, patient history information and set of variables). Lapointe et al., page 8, paragraph 0097, page 21, paragraphs 0034-0360 wherein each element (i.e., variable) is associated with an impact parameter for a clinical conclusion (i.e. a low, high or moderate risk of preterm delivery within a time frame). Lapointe et al., page 10, paragraphs 0110, 0113.

b. for each element, generating a confidence parameter (i.e., a calculated risk value as a function of the conclusion. Lapointe et al. Fig 11A, paragraphs 0322-

determining an overall level of confidence parameter (i.e., risk report with calculated risk value(s) for associated interpretations such as low, high or moderate for a clinical conclusions (i.e.. a low, high or moderate risk of preterm delivery within a time frame) as a function of each of the confidence parameter and the associated impact values shown in Fig 11A, B and page 19, paragraphs 0311-0313 of Lapointe et al.

Response to Arguments

7. Applicant's arguments filed on September 1, 2006 have been fully considered but they are not persuasive. The arguments will be addressed in sequential order as they were presented in the "Remarks" section.

The applicants argue that Lee does not teach the following features: "A method for determining an overall level of confidence for a medical clinical conclusion comprising and determining an overall level of confidence parameter as a function of each confidence parameter and associated impact value." However, the examiner would like to note that these limitations are recited in the preamble rather than the body of the claim and are therefore not given patentable weight. The examiner recommends amending the claims to recite these limitations more actively in the body of the claims.

Applicants argue that Lee and LaPointe do not teach, suggest or provide any information that would render it obvious to one of ordinary skill in the art to "determining an overall level of confidence parameter as a function of each confidence parameter and associated impact value." However, Lee does in fact teach this feature (Detailed Description, Paragraph 142). The applicants have not explained why "taking steps to improve the accuracy of a medical conclusion such as whether a slide contains normal or abnormal cells is not the same as determining the overall level of confidence." The applicants have not explained clearly what concept or limitation they are attempting to claim with the use of the limitation "determining an overall level of confidence parameter as a function of each confidence parameters and the associated impact values."

Examiner's Suggestions

8. The examiner recommends filing a Request for Continued Examination (RCE) for this application and making the following changes to the claims:

Several formulas and mathematical relationships are described on pages 15-18 of the specification. This section of the specification appears to explain and set forth the core inventive concept of this application, however, these concepts are not claimed in any of the claims. The examiner recommends more actively claiming these features and concepts in the claims. However, any amendment to the claims will be subject to a new and/or updated prior art search before the indication of any allowable subject matter.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

12/28/2006

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER